K070227 Page 1 of 2

510(K) SUMMARY

ARTHROCARE CORPORATION
OPUS MAGNUM PI KNOTLESS FIXATION DEVICE

APR 16 2007

General Information

Submitter Name/Address:	ArthroCare Corporation 680 Vaqueros Avenue Sunnyvale, CA 94085-3523
Establishment Registration No.:	2951580
Contact Person:	Laura N. Kasperowicz Sr. Manager, Regulatory Affairs
Date Prepared:	January 23, 2007

Device Description

Trade Name:	Opus® Magnum™ PI
Generic/Common Name:	Bone Anchor, Fastener, Fixation, Soft Tissue
Classification Name:	Fastener, Fixation, Nondegradeable, Soft Tissue (Class II per 21 CFR 888.3040, Product code: MBI)

Predicate Devices

Opus Magnum	K012125 (Cleared 09/17/01)
Opus LabraLock P	K061349 (Cleared 07/14/06)

Product Description

The Opus® Magnum™ PI device is a bone anchor with inserter handle designed for specific indications in arthroscopic and orthopedic procedures.

Indications For Use

The Opus® Magnum™ PI bone anchor with inserter is indicated for use in fixation of soft tissue to bone. Examples of such procedures include:
Shoulder: Bankart Repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule shift/capsule-labral reconstruction, biceps tenodesis and deltoid repair
Ankle: Lateral instability, medial instability, Achilles tendon repair/reconstruction and midfoot reconstruction
Foot: Hallux valgus reconstruction
Elbow: Tennis elbow repair, biceps tendon attachment
Knee: Extra-capsular repairs; reattachment of: medial collateral ligament, posterior oblique ligament or joint capsule closure to anterior proximal tibia; extra capsular reconstruction, ITB tenodesis; patellar ligament and tendon avulsions

510(K) SUMMARY

Substantial Equivalence

By definition, substantial equivalence means that a device has the same intended use and technical characteristics as the predicate device, or has the same intended use and different technological characteristics, but can be demonstrated to be as safe and effective as the predicate device. The Opus® Magnum™ PI design and technology is substantially equivalent to the existing Opus® Magnum™ Knotless Fixation Device cleared by the Food & Drug Administration [K012125, and subsequently amended by K020172, K031083 and K042914]. The Opus® Magnum™ PI material is substantially equivalent to the existing Opus® LabraLock™ P Knotless Fixation Device cleared by the Food & Drug Administration [K061349]. The differences between the Opus® Magnum™ PI and the predicate devices do not raise any questions regarding the safety and effectiveness of the implant. Furthermore, the materials are well characterized and have been used in predicate devices with similar indications. The device, as designed, is as safe and effective as predicate devices.

Summary and Reason for 510k Notification

The purpose of this 510k is to notify the Food and Drug Administration of a new product, the Opus® Magnum™ PI Knotless Fixation Device. This new product is substantially equivalent to the Opus® Magnum™ Knotless Fixation Device originally cleared under K012125 [and subsequently amended by K020172, K031083 and K042914], but is manufactured from PEEK (polyether-etherketone) as opposed to stainless steel.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ArthroCare Corporation
% Ms. Laura N. Kasperowicz
Senior Manager, Regulatory Affairs
680 Vaqueros Avenue
Sunnyvale, California 94085-3523

APR 16 2007

Re: K070227
Trade/Device Name: Opus® Magnum™ PI Knotless Fixation Device
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI, HWC
Dated: January 23, 2007
Received: January 24, 2007

Dear Ms. Kasperowicz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or 240-276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

page 1 of 1

INDICATIONS FOR USE STATEMENT

510(k) Number: K070227

Device Name: Opus® Magnum™ PI Knotless Fixation Device

Indications for Use:

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Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	NO

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070227